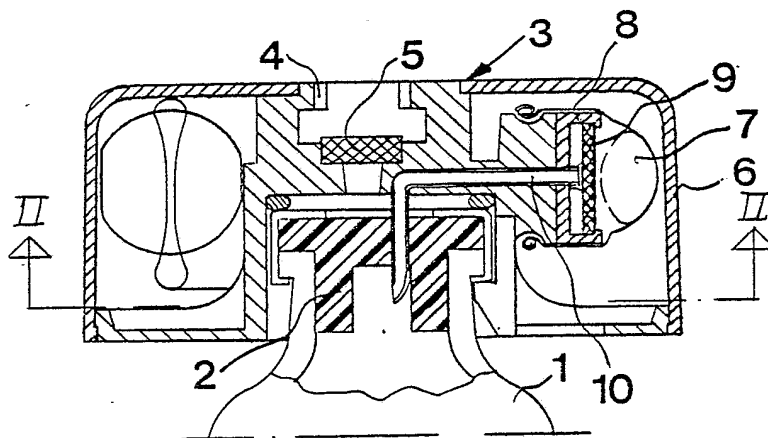


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(54) Title: A PRESSURE BALANCING DEVICE FOR SEALED VESSELS



(57) Abstract

Device for ventilating and pressure balancing the interior of a sealed vessel (1) containing a substance which is to be taken out from said vessel e.g. by an injection syringe, said vessel being provided with a closure means (2) comprising a sealing member (2) through which a puncturing member, e.g. a needle can be passed for entering the interior of said vessel. The closure means (2) or a connection means (3) attachable onto said vessel is provided with ventilating means (10; 13; 14, 15) arranged to provide a communication between the interior of the vessel (1) and a closed container or alternatively the atmosphere via a filter (16).

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A PRESSURE BALANCING DEVICE FOR SEALED VESSELS

Technical field

05 The present invention refers to a device for ventilating and
pressure balancing the interior of a sealed vessel containing
a substance which is to be taken out from said vessel e.g. by
an injection syringe, said vessel being provided with a
closure means comprising a sealing member through which a
10 puncturing member, e.g. a needle can be passed for entering
the interior of said vessel.

Background of the invention

15 Drugs and medicines of different kinds which are to be injected
into a patient are usually delivered in vials sealed by a
membrane or sealing plug which can be penetrated by the needle
of an injection syringe. The substances are in some cases
delivered as solutions and in other cases as dry substances,
20 which firstly have to be dissolved in a solvent, e.g. water,
which is injected into the vial by an injection springe. In
both cases there are pressure balancing problems when pressing
liquid into or taking liquid out from the air-tightly sealed
vial.

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The object of the invention and its most important features

The object of the present invention is to provide a pressure
balancing system especially intended for vials containing
30 toxic substances, such as cytotoxic drugs, etc., which are not
allowed to contaminate the ambient air. This has according to
the invention been achieved by the fact that said closure
means or a connection means attachable onto said vessel is
provided with ventilating means arranged to provide a communi-
35 cation between the interior of the vessel and a closed
container or alternatively the atmosphere via a filter.



Brief description of the drawings

Fig. 1 is a longitudinal section of a closure means to a vial according to the present invention.

05 Fig. is a section according to the line II-II in fig. 3.

Fig. 3-5 is a longitudinal sections through three other embodiments.

Description of some embodiments

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Referring to the drawings the numeral 1 denotes a vial sealed by a stopper 2. A connection means 3 is attached to the bottle-neck of the vial 1. The connection means 3 has a bayonet coupling 4 for receiving a transferring member (not shown) of the kind disclosed in the Swedish patent application No. 8301176-7 and International patent application No. PCT/SE84/00075 and for transferring the content of the vial to an injection syringe without any contamination risk. A sealing member 5, e.g. of Teflon R, which can be penetrated by a needle is provided in the connection means 3, which further is provided with a hood 6 extending radially a considerably distance outside the bottle-neck of the vial 1. A torus-shaped expandable balloon 7 is placed under the hood 6 and attached to a cylindrical balloon attachment 8 provided with a liquid-rejecting filter 9. The balloon 7 communicates with the interior of the vial 1 via a hollow needle 10 passed through the stopper 2. The balloon attachment 8 could of course be angled at which angling of the balloon 7 is avoided.

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The balloon 7 works as a pressure equalizer when handling the contents of the vial 1. In case the vial 1 contains a dry substance this must firstly be dissolved in a solvent, e.g. water, which is injected with an injection syringe. This will create an overpressure in the vial 1 and the surplus air is then pressed into the balloon 7. On sucking up the dissolved substance into the injection syringe air is sucked back into the vial from the balloon and a negative pressure is avoided. A completely closed pressure equalization system has thus been



achieved.

In inflated condition the walls of the balloon 7 are stretched and they exert a counter-pressure on the volume of air contained therein.

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According to the embodiment shown in fig. 3 the connection means 3 is provided with a pointed member 11 passed through the stopper 2 of the vial 1. The pointed member 10 is provided with two passages 12 and 13, one 12 for a needle (not shown) for transferring the substance contained in the vial to an injection syringe and the other 13 for ventilating the vial 1. The ventilating passage 13 communicates with a free space 14 between the connection means 3 and vial 1 and a further passage 15 in the connection means 3. Said further passage 15 communicates with the atmosphere via a liquid-rejecting filter 16. This filter is preferably of a type also preventing the vapour of the substance contained in the vial to pass therethrough, which is especially important if the substance is toxic. An example of such a filter is HEPA - high efficiency particulate air filter of 10,3 micron.

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In fig. 4 is shown an embodiment similar to the one according to fig. 3, but it lacks the pointed member 11. Communication between the interior of the vial 1 and the passage 14 can be achieved by the needle (not shown) for transferring the substance to an injection syringe. Said needle can be provided with ventilation means of different kinds as described in the International Application No. PCT/SE84/00075.

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The connection means 3 is further on its outside provided with a ring-shaped attachment 17 for a ring-shaped flexible member 7 inflatable like a balloon and arranged to cover the filter 16.

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In fig. 5 is shown a combination of two further embodiments similar to the one according to fig. 1, but here according to one of the embodiments the flexible member communicating with the interior of the vial 1 via the hollow needle 10 consists

BAD ORIGINAL



of a bellows 18 instead of a balloon 7. The bellows 18 is attached to the lower edges of the hood 6 so that a closed space is provided under said hood. The bellows is pressure-less both in retracted and extended condition. Instead of a bellows a piston-cylinder or similar arrangement, the volume of which is variable, can be used. According to the other embodiment shown in fig. 5 the interior of the vessel communicates with a space closed by a lid 19 and the volume of which is constant. If the volume of said space is sufficient it can serve as a pressure-balancer or buffer for the vessel.

The invention is of course not limited to the embodiments shown and described, but a number of modifications are possible within the scope of the claims. Thus in cases where nontoxic substances are handled the membrane 5 and coupling means 4 for a transferring member can be eliminated.



C L A I M S

1. A device for ventilating and pressure balancing the interior of a sealed vessel (1) containing a substance which is to be taken out from said vessel e.g. by an injection syringe, said vessel being provided with a closure means (2) comprising a sealing member (2) through which a puncturing member, e.g. a needle can be passed for entering the interior of said vessel,

characterized in, that said closure means (2) or a connection means (3) attachable onto said vessel is provided with ventilating means (10;13;14,15) arranged to provide a communication between the interior of the vessel (1) and a closed container (7;18;19), or alternatively the atmosphere via filter.

2. A device according to claim 1, characterized in, that said container consists of a balloon (7) having extensible side walls and which in inflated condition exerts a counterpressure on the volume of air contained therein.

3. A device according to claim 1, characterized in, that said container consists of a bellows (18), piston-cylinder or the like, the volume of which is variable and which is pressure-less in both retracted and extended position.

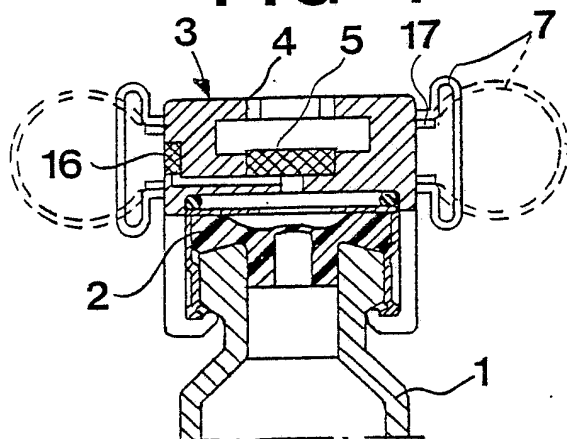
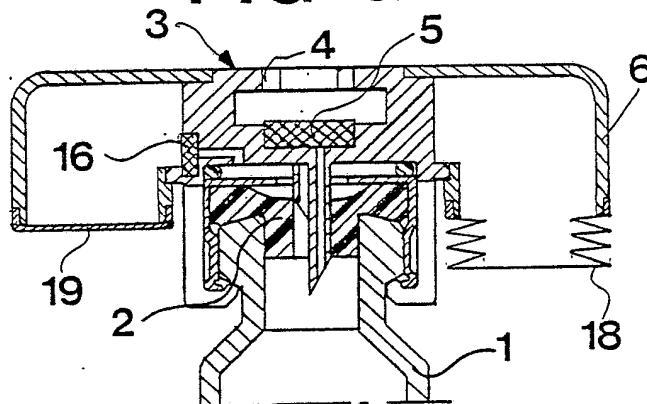
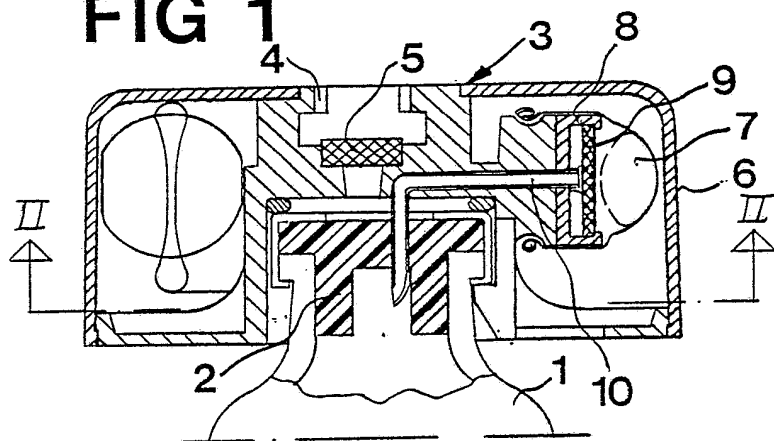
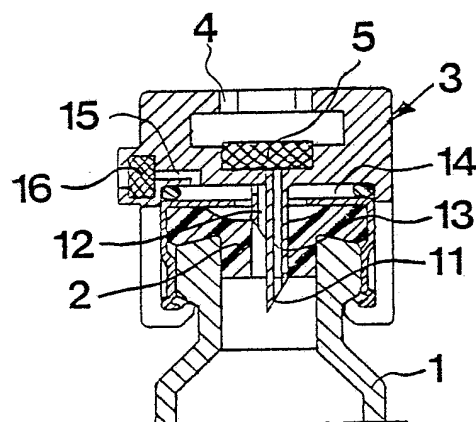
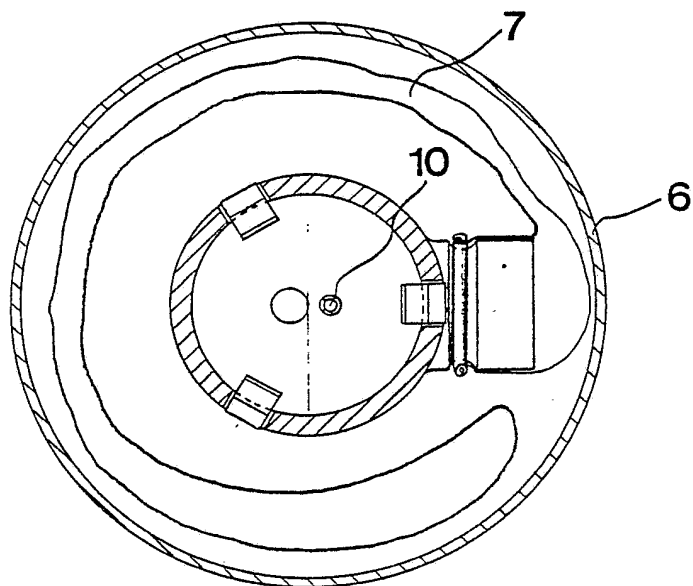
4. A device according to claim 1, that the volume of said container is constant.

5. A device according to any of the preceding claims, characterized in, that said connection means (3) is provided with a hollow needle (11) arranged to penetrate the sealing member (2) of the vessel (1) when attaching the connection means to the vessel, said needle constituting said ventilating means.



6. A device according to any of claims 1-4,
c h a r a c t e r i z e d i n,
that said connection means (3) is provided with a hollow
pointed member (11) arranged to penetrate the sealing member
055 (2) of the vessel (1) when attaching the connection means to
the vessel, said pointed member having a passage (12) through
which the interior of the vessel can be reached by said
puncturing member, e.g. a needle, and a further ventilating
passage (13) making a part of said ventilating means.



FIG 4**FIG 5****FIG 1****FIG 3****FIG 2**

INTERNATIONAL SEARCH REPORT

International Application No PCT/SE84/00195

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) ¹ According to International Patent Classification (IPC) or to both National Classification and IPC ² <div style="margin-top: 5px;">A 61 J 1/00</div>														
II. FIELDS SEARCHED <div style="text-align: center; margin-top: 5px;">Minimum Documentation Searched ⁴</div> <table border="1" style="width: 100%; border-collapse: collapse; margin-top: 5px;"> <tr> <th style="width: 25%;">Classification System</th> <th style="width: 75%;">Classification Symbols</th> </tr> <tr> <td style="padding: 5px;">IPC</td> <td style="padding: 5px;">A 61 J 1/06, 5/00, 1/00, 3/00</td> </tr> <tr> <td style="padding: 5px;">US C1</td> <td style="padding: 5px;"><u>128:272.3</u></td> </tr> </table> <div style="margin-top: 5px; text-align: center;">Documentation Searched other than Minimum Documentation to the Extent that such Documents are included in the Fields Searched ⁵</div> <div style="margin-top: 10px; padding: 5px;">SE, NO, DK, FI classes as above</div>			Classification System	Classification Symbols	IPC	A 61 J 1/06, 5/00, 1/00, 3/00	US C1	<u>128:272.3</u>						
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III. DOCUMENTS CONSIDERED TO BE RELEVANT ¹⁴ <table border="1" style="width: 100%; border-collapse: collapse; margin-top: 5px;"> <tr> <th style="width: 10%;">Category ⁶</th> <th style="width: 60%;">Citation of Document, ¹⁶ with indication, where appropriate, of the relevant passages ¹⁷</th> <th style="width: 30%;">Relevant to Claim No. ¹⁸</th> </tr> <tr> <td style="text-align: center; vertical-align: top; padding: 5px;">X</td> <td style="padding: 5px;">SE, B, 341 982 (STORA KOPPARBERG BERGSLAGS AB) 24 January 1972</td> <td style="vertical-align: top; padding: 5px;">1-2, 4-6</td> </tr> <tr> <td style="text-align: center; vertical-align: top; padding: 5px;">X</td> <td style="padding: 5px;">FR, A, 2 221 121 (COMPASELECT G M B H) 11 October 1974</td> <td style="vertical-align: top; padding: 5px;">1-2, 4-6</td> </tr> <tr> <td style="text-align: center; vertical-align: top; padding: 5px;">X</td> <td style="padding: 5px;">EP, A2 0 091 312 (BAXTER TRAVEROL LAB) 12 october 1983</td> <td style="vertical-align: top; padding: 5px;">1-2</td> </tr> </table>			Category ⁶	Citation of Document, ¹⁶ with indication, where appropriate, of the relevant passages ¹⁷	Relevant to Claim No. ¹⁸	X	SE, B, 341 982 (STORA KOPPARBERG BERGSLAGS AB) 24 January 1972	1-2, 4-6	X	FR, A, 2 221 121 (COMPASELECT G M B H) 11 October 1974	1-2, 4-6	X	EP, A2 0 091 312 (BAXTER TRAVEROL LAB) 12 october 1983	1-2
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<div style="display: flex; justify-content: space-between;"> <div style="width: 45%;"> <p>¹⁹ Special categories of cited documents:</p> <p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier document but published on or after the international filing date</p> <p>"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p> </div> <div style="width: 45%;"> <p>"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</p> <p>"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step</p> <p>"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.</p> <p>"&" document member of the same patent family</p> </div> </div>														
IV. CERTIFICATION <table border="1" style="width: 100%; border-collapse: collapse; margin-top: 5px;"> <tr> <td style="width: 50%; padding: 5px;"> Date of the Actual Completion of the International Search ¹ <div style="margin-top: 5px;">1984-08-17</div> </td> <td style="width: 50%; padding: 5px;"> Date of Mailing of this International Search Report ² <div style="margin-top: 5px; text-align: center;">1984-08-28</div> </td> </tr> <tr> <td style="padding: 5px;"> International Searching Authority ¹ <div style="margin-top: 5px;">Swedish Patent Office</div> </td> <td style="padding: 5px;"> Signature of Authorized Officer ²⁰ <div style="margin-top: 5px; text-align: center;"> Agneta Anggård </div> </td> </tr> </table>			Date of the Actual Completion of the International Search ¹ <div style="margin-top: 5px;">1984-08-17</div>	Date of Mailing of this International Search Report ² <div style="margin-top: 5px; text-align: center;">1984-08-28</div>	International Searching Authority ¹ <div style="margin-top: 5px;">Swedish Patent Office</div>	Signature of Authorized Officer ²⁰ <div style="margin-top: 5px; text-align: center;"> Agneta Anggård </div>								
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